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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,049	06/21/2001	Kevin P. Francis	PXE-013.US; 9400-0013	6970
23419	7590	05/18/2004	EXAMINER	
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,049

Applicant(s)

FRANCIS ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 43,44 and 53-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42,45, 47-52,58 and 59 is/are rejected.
- 7) ☐ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed March 1, 2004.

Amendments were made to the claims.

Claims 1-59 are pending in the instant application. Claims 43, 44 and 53-57 are withdrawn as being drawn to a non-elected invention. Any rejection of record in the previous Office Action, mailed November 26, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Election/Restrictions

Applicant continues to traverse the Election/Restriction requirement, based on the allegation that the inventions overlap, therefore a search of one invention would necessarily turn up art on the other. This argument is inaccurate, as evidenced by the definition of the terms "overlapping" and "commensurate" (Definitions provided by Merriam-Webster OnLine). "Overlapping" means "to lie or extend over a portion, or have an area or range in common," whereas "commensurate" means of the same size extent or duration thereof." In order for a search of one invention to necessarily turn up art on another invention, they must be commensurate. To be overlapping is insufficient because an art search may turn up art on one invention in a portion that is not overlapping with the other invention, and *vice versa*. In order to ensure that the full scope of the claims is searched, the Office would have to perform distinct

Art Unit: 1636

searches when two inventions that merely overlap are concerned, in order to ensure a search of the areas that do not overlap. The Office cannot simply search the area that is shared between the inventions because there may be art on one or both of the inventions in the non-overlapping areas. Importantly, it is again noted and restated that the different classifications set forth in the Restriction shows the requirement for different searches, and this is sufficient to establish a search burden. This need for more than one search is burdensome to the Office, therefore the Election/Restriction requirement is still deemed proper. Applicant is reminded that the Finality of the Election/Restriction requirement set forth in the previous Office Action is still in effect.

Claim Objections

Claim 46 is objected to because of the following informalities: claim 46 is dependent on a claim that is withdrawn as being drawn to a non-elected invention. This claim is withdrawn from consideration until such time as the dependency is changed. Appropriate correction is required. **This objection is maintained for the same reasons set forth in the previous Office Action and above concerning the Election/ Restriction requirement.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-42, 45, 47-52, 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1636

applicant regards as the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

It is noted that the claims have not been amended to remove the term “derived” from the claim (as stated by Applicant in their arguments), thus the claims stand rejected for the reasons set forth in the previous Office Action. Applicant traverses the grounds of this rejection, stating that one of skill in the art would readily understand what is meant by the term “derived.” Importantly, when a chemical compound is “derived,” the resulting product is a “derivative.” The definition of the term “derivative”, as it relates to a chemical composition (such as a nucleic acid) indicates a “substance that can be made from another substance.” As stated in the previous Office Action, it is unclear what steps need to be taken in order to make one substance from another; i.e., what are the chemical modifications to be made while the product is “derived.” As such, the rejection is still found proper in the face of Applicant’s provision of the definition for “derived,” based on the definition of “derivative.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13, 23 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Knudtson (as set forth in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed March 1, 2004 have been fully considered but they are not persuasive. Applicant provides the following ground of traversal:

1. Applicant asserts that the Office errs in applying Knudtson as anticipatory art because Knudtson teaches cassettes that are expressed in Mycoplasma, which are gram-negative organisms. As a result, Applicant asserts that Knudtson simply "does not describe or demonstrate transposons that are functional in gram-positive bacteria." See for example Applicant's arguments on pages 16-17.

Applicant's traversal has been fully considered, but is not found convincing for the following reasons:

1. Firstly, Applicant has misinterpreted their claim as a method of using, and not as a product. While Knudtson teaches using a transposon cassette in mycoplasma, the cassette itself is obviously functional in gram-positive bacteria. This is evidenced, as pointed out in the previous Office Action, by the fact that the transposon in question constitutes nucleotide sequences isolated from a gram-positive bacterium. Indeed, the TN4001 transposon that is used by Knudtson is isolated from *S. aureus*, which is a gram-positive bacterium; thus these sequences *must* be functional in gram-positive bacterium. The fact that Knudtson teaches using the transposon cassette in mycoplasma, which is not a gram-positive bacterium, is irrelevant, as the claims are drawn to a product, and not a method.

Secondly, the transposon used in Knudtson is TN4001, which Applicant claims as a limitation in claim 2 of the instant application. If Knudtson indeed does not teach a transposon cassette that is functional in gram-positive bacterium, then Applicant's claimed invention lacks enablement for at least said claim 2. However, this is clearly not the case because the transposon and internal sequence that are in question are both functional in gram-positive bacterium, as stated above.

Finally, it is worth noting that the claims as written simply indicate, "said first sequence of interest capable of being expressed in a gram-positive target organism" (see line 5-7 of claim 1 as currently amended). When given the broadest reasonable interpretation, this does not mean that the entire transposon cassette needs to be functional in gram-positive bacterium, as Applicant appears to be arguing. What it simply means is that the first sequence can be expressed in a gram-positive bacterium, and since all known organisms use the same nucleotides (A, C, G, T) for encoding polypeptide sequences, any polynucleotide sequence can be functionally expressed in a gram-positive bacterium. Even if one attempts to argue that without a functional transposon cassette, there would be no expression of the internal polynucleotide sequence, there can still be expression by a non-transposon mediated integration (e.g., recombination) of the internal polynucleotide sequence into a genomic sequence where expression is achieved. Therefore, Applicant's argument that the transposon cassette taught by Knudtson lacks functionality in gram-positive organisms is a misreading of the functional language in the claim.

In conclusion, Applicant's argument that Knudtson does not teach a transposon cassette that is functional in gram-positive bacterium is unconvincing for several reasons. First, the entire

Art Unit: 1636

sequence taught by Knudtson is based on sequences that were isolated from gram-positive bacterium. Second, Knudtson actually uses sequences that are limitations in dependent claims, therefore it seems necessary that the transposon taught by Knudtson is functional in gram-positive bacterium, otherwise Applicant's invention would not be enabled. Finally, it is noted that Applicant appears to be misplacing the functional language of the claim on the entire cassette, as opposed to the polypeptide encoding sequence (where the emphasis is on according to the claim language). Applicant is reminded that the manner in which a product is used does not change the nature of the product; the fact of the matter is that Knudtson teaches the product claimed by Applicant, regardless of how they use it (i.e., in a gram-negative bacterium as opposed to a gram-positive bacterium).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-5, 14-15, 50-52 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudtson (as applied to claim 1, as well as claims 2, 3, 13, 23 and 47) in view of Lajoie (as presented in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Art Unit: 1636

Claims 6-10, 16, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudtson in view of Lajoie (as applied to claim 4, as well as claims 1-3, 5, 13-15, 23, 47, 50-52 and 58) and in further view of Jacobs (as set forth in the previous Office Action. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudtson and Lajoie in view of Jacobs (as applied to claim 7, as well as claims 1-6, 8-10, 13-16, 23, 47-52 and 58), and in further view of Baldwin (as set forth in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claims 17, 18 and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Knudtson and Lajoie in view of Jacobs (as applied to claim 4, 15, and 16, as well as claims 1-3, 5-10, 13, 14, 23, 47-52 and 58), and in further view of Wagner (as applied in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed March 1, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. The entire basis for Applicant's traversal of each rejection under 35 USC § 103(a) is the lack of teachings provided by Knudtson. Applicant then states that the secondary references fail to supply the elements that are missing from Knudtson, making the rejection is improper.

Applicant's traversal has been fully considered, but is not found convincing for the following reasons:

1. As addressed above in the response to the traversal of the rejection under 35 USC § 102(b), Knudtson does indeed teach all of the elements of the claim, despite Applicant's arguments. Since Knudtson does teach the elements Applicant indicates as absent from the combined teachings, this cannot be the ground for traversal of the instant rejection. Thus, absent any additional evidence to the contrary, the rejections under 35 USC § 103(a) are deemed proper.

Allowable Subject Matter

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER